

<b>UNITED STATES BANKRUPTCY COURT</b> <b>DISTRICT OF NEW JERSEY</b> Caption in Compliance with D.N.J. LBR 9004-1(b)	
<b>U.S. Department of Justice – Civil Division</b>  <b>Commercial Litigation Branch</b> Kirk T. Manhardt Mary A. Schmergel Leah V. Lerman P.O. Box 875, Ben Franklin Station Washington, DC 20044-0875 (202) 307-0452 leah.v.lerman@usdoj.gov  <i>Attorneys for the United States of America</i>	
In re:  Nostrum Laboratories, Inc.  Debtor.	Chapter 11  Case No. 24-19611 (JKS)  Judge: John K. Sherwood  Hearing Date: April 8, 2025  Objection Deadline: April 8, 2025

**UNITED STATES OF AMERICA’S LIMITED  
OBJECTION TO THE DEBTOR’S SALE MOTION**

The United States of America (the “United States”) files this Limited Objection to the Debtor’s Motion Pursuant to Sections 105(a), 363 and 365 of the Bankruptcy Code and Bankruptcy Rules 2002, 6004 and 6006 for an Order Approving the Sale of Debtor’s Assets Free and Clear of Liens, Claims and Encumbrances and the Assumption and Assignment of Executory Contracts (the “Sale Motion”) [Dkt. No. 337], and in support thereof states as follows:

### **Factual Background**

1. On September 30, 2024 (the “Petition Date”), the debtor Nostrum Laboratories, Inc. (the “Debtor”) filed a voluntary petition for bankruptcy under chapter 11 of Title 11 of the United States Code (the “Bankruptcy Code”).

2. The Debtor owns and operates a generic drug manufacturing business, including two manufacturing facilities, that is regulated by various agencies of the United States, including the U.S. Department of Health and Human Services (“HHS”) and the U.S. Drug Enforcement Administration.

3. Pursuing a sale of substantially all its assets, the Debtor solicited bids from potential buyers. An auction to determine highest and best offers was conducted on April 1, 2025, and a notice of the outcome was filed on April 3, 2025. *See* Dkt. No. 336.

4. On April 4, 2025, the Debtor filed its Sale Motion and requested a hearing to approve such motion on April 8, 2025.

### **Limited Objection**

5. The Debtor operates in a highly regulated industry where the transfer of assets may trigger obligations on the part of both the Debtor and buyer. The HHS’s Food and Drug Administration (“FDA”) administers drug manufacturing programs and regulates manufacturers such as the Debtor.

6. Pursuant to the Sale Motion, several different asset types are being transferred, including the facilities, drug products, abbreviated new drug applications (“ANDAs”) and equipment. Each asset type concerns different regulatory requirements.

7. The Debtor operates two drug manufacturing facilities, one in Bryan, OH and one in Kansas City, MO. When facilities are transferred to new owners, both the prior and new owner

must provide notice to the FDA. 21 C.F.R. § 207.29. According to the Sale Motion, different buyers are purchasing these two facilities.

8. Additionally, when drug products are sold, the manufacturer must provide notice of any such changes to the FDA. 21 C.F.R. § 207.57. According to the Sale Motion and discussions with the Debtor's counsel, six separate buyers are purchasing various drug products. The Debtor must properly notify FDA of the changes to its product list.

9. Finally, when ANDAs are transferred to new owners, the prior and new owner must provide the FDA with notice of the change of ownership. 21 C.F.R. § 314.72. Thus, the Debtor and the buyers of the various ANDAs are required to submit certain information to the FDA evidencing that the ANDAs are under new ownership.

10. However, despite these various regulatory requirements associated with the different assets being sold pursuant to the Sale Motion, the proposed sale order contains certain provisions that could be misinterpreted broadly to mean that the Debtor's assets may be sold free and clear of these regulatory requirements. *See e.g.*, ¶ 8, Dkt. No. 337-2.

11. The Sale Motion cannot be approved until the United States' police and regulatory powers are properly preserved and the proposed sale order ensures that the Debtor and buyers comply with all notice requirements.

12. To satisfy its concerns, the United States provided the following language to the Debtor's counsel to include in the proposed sale order:

*Notwithstanding any provision to the contrary in this Sale Order ("Order"), any Asset Purchase Agreement, or any other document related to the Sale Transaction, nothing shall:*

- i. release, nullify, preclude or enjoin the enforcement of any police or regulatory power or any liability that any entity would be subject to as the owner, lessor, lessee or operator of property that such entity owns, operates or leases after the date of entry of this Order;*

- ii. *affect the setoff or recoupment rights of the United States;*
- iii. *confer exclusive jurisdiction to the Bankruptcy Court except to the extent set forth in 28 U.S.C. § 1334 (as limited by any other provisions of the United States Code);*
- iv. *authorize the assumption, assignment, sale or other transfer of any federal (a) grants, (b) grant funds, (c) contracts, (d) agreements, (e) awards, (f) task orders, (g) property, (h) intellectual property, (i) patents, (j) leases, (k) certifications, (l) applications, (m) registrations, (n) billing numbers, (o) national provider identifiers, (p) provider transaction access numbers, (q) licenses, (r) permits, (s) covenants, (t) inventory, (u) guarantees, (v) indemnifications, (w) data, (x) records, or (y) any other interests belonging to the United States (collectively, "Federal Interests") without compliance by the Debtor and Purchasers with all terms of the Federal Interests and with all applicable non-bankruptcy law;*
- v. *be interpreted to set cure amounts or to require the United States to novate, approve or otherwise consent to the sale, assumption, assignment or other transfer of any Federal Interests;*
- vi. *waive, alter or otherwise limit the United States' property rights; or*
- vii. *expand the scope of 11 U.S.C. § 525.*

*In the event of an inconsistency or conflict between any provision of the Asset Purchase Agreement and any provision of this Order, as to the United States, the provisions of this Order and federal law shall govern.*

13. The United States understands that the Debtor has no objection to this language and that the language is being reviewed by counsel to the various buyers.

#### **Reservation of Rights**

The United States reserves all rights to supplement this objection as further information becomes known or the proposed sale order is further amended.

WHEREFORE, the United States respectfully requests that this Court deny the Sale Motion unless the United States' reservation of rights language is included in the proposed sale order.

Dated: April 8, 2025

Respectfully submitted,

YAAKOV ROTH  
Acting Assistant Attorney General

/s/ Leah V. Lerman  
KIRK T. MANHARDT  
MARY A. SCHMERGEL  
LEAH V. LERMAN  
Civil Division, Commercial Litigation Branch  
U. S. Department of Justice  
P. O. Box 875  
Ben Franklin Station  
Washington, DC 20044-0875  
(202) 307-0452  
[Leah.V.Lerman@usdoj.gov](mailto:Leah.V.Lerman@usdoj.gov)

ATTORNEYS FOR THE UNITED STATES

**CERTIFICATE OF SERVICE**

On April 8, 2025, I caused a copy of the foregoing to be served electronically through the Court's ECF system upon those who have entered an appearance in this proceeding.

/s/ Leah V. Lerman

Leah V. Lerman

Commercial Litigation Branch

Civil Division

United States Department of Justice